UNITED STATES SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

BE IT KNOWN THAT I, **Franz KONRAD, of A-4690 Oberndorf bei Schwanenstadt, Sonnenweg 6, Austria (AT), Austrian citizen,**

have invented certain new and useful improvements in

"CONTAINER SYSTEM AND CLOSURE DEVICE COMPRISING A SEALING DEVICE AND CAP"

of which the following is a specification.

BACKGROUND OF THE INVENTION

1. Field of the invention

The invention relates to

- a cap for a closure device, designed to receive a sealing device which can be pierced, and has at least one external surface with at least certain regions which can be inserted in an open end face of the housing container forming a sealing surface, with at least two coupling parts joined thereto so as to be displaceable, which are spaced apart from one another in the direction of a longitudinal axis and project out from an internal face of a cap casing in planes perpendicular to this longitudinal axis in the radial direction towards the longitudinal axis, forming a locating region between them, and having at least a first end which is open,

- a sealing device for a closure device affording a retaining action in a locating region formed inside a cap, having a sealing element with a sealing surface which co-operates with at least certain regions of an open end face of a housing container, radially outwards from which extends at least one, preferably continuous, flange-type shoulder, the flange-type shoulder constituting a first end region and the sealing element constituting another end region,

- a closure device for an open end face of a housing container, in particular for body fluids,

- as well as a container system, in particular for body fluids, with a housing container having at least one open end face which is closed off by a closure device.

2. The Prior Art

Patent specification EP 0 419 490 B1 filed by the same applicant discloses a closure device for a cylindrical housing with an open end lying opposite a closed end, which can be evacuated. This closure device comprises a cap which fits on an end face of the cylindrical housing and has an end wall in which a bore is disposed. The closure device additionally has a sealing device which can be pierced, with a sealing surface disposed between the bore and an internal bearing surface of the cylindrical housing. A flange-type locating projection of the sealing device projects radially outwards from this sealing surface and is supported between two projections of the cap. In conjunction with the locating projection, these projections constitute coupling parts of a coupling mechanism between the cap and the sealing device. Accordingly, two projections project out from the cylindrical internal face of the cap in the direction towards the longitudinal axis forming a groove-shaped locating region for the flange-type locating projection, the projection facing the housing being disposed between the end face of the housing and the locating projection. With this system, the flange-type locating projection is not always guaranteed to remain securely retained in the groove-shaped locating region of the cap in all applications.

Another closure device for a cylindrical housing is disclosed in patent specification EP 0 445 707 B1, also filed by the same applicant. The closure device in this case is used to close off an open end face of a cylindrical housing and in particular one which can be evacuated, the closure device comprising a tubular shaped cap which fits round the end face of the cylindrical housing and a sealing device inserted in the end face opening. The sealing device is then joined to the cap and/or the cylindrical housing by means of a coupling mechanism, the coupling mechanism consisting of two coupling parts, preferably

in the form of flange-type projections, joined to the cap so that they can be displaced, and which project out from the cylindrical internal face of the cap in the radial direction forming a groove-shaped locating region between them. The sealing device also has a coupling part in the form of a flange-type shoulder which is inserted in the groove-shaped locating region. The closure device also has a retaining ring, in particular a washer or clamping ring, which is pushed inwards in the direction towards the longitudinal axis, through the cylindrical housing orifice of the cap, when biassed by the coupling part of the sealing device disposed between the latter and the projection at the end remote from the housing. This retains the sealing device so that it is prevented from twisting and/or shifting in the longitudinal direction of the cylindrical housing. To this end, a thickness of the flange-type shoulder of the sealing device constituting the coupling part is thicker in the non-assembled state than a distance between the two projections in the direction of the longitudinal axis, less the thickness of the retaining ring. Yet again, it has been found that it is not always possible to retain the flange-type shoulder of the sealing device properly in the groove-shaped locating region of the cap so that it remains secure and safe in all applications.

SUMMARY OF THE INVENTION

The objective of the present invention is to propose a cap for a closure device, a sealing device for a closure device, a closure device resulting therefrom and a container system, in which the coupling mechanism between the cap and sealing device is virtually prevented from coming loose during use, in particular during filling or taking samples.

This objective is achieved by the invention due to the fact that an internal clearance dimension, in particular an internal diameter, of the first coupling part co-operating with the sealing surface is between 5 % and 25 % smaller than an external dimension, in particular an external diameter, of the sealing device to be located by the region of its sealing surface in the non-deformed or non-biased state. The surprising advantage obtained as a result is that when the closure device is pierced with hollow needles or cannulas, which tend to have a larger external diameter, the flange-type shoulder of the sealing device is not pulled out of the locating region or at least is so in certain regions only. This situation usually occurs when using automated sample-taking systems, with which sampling needles or cannulas with an external diameter of between 0.8 mm and 2.5 mm, or even bigger up to 3.5 mm or 4.0 mm, are used, and not only is the sealing device pulled out of the locating region, at least some parts of it are also pulled into the interior of the housing container. Pinching the sealing device in the region of its sealing surface enables it to be retained more securely in the cap, making it less likely to be pulled out. This is also of importance once the sample has been taken because it enables the cap to be removed from the housing container with the sealing device still intact within it, significantly reducing or totally preventing any risk of contamination due to unintentional contact with the sample contents.

However, the objective is also independently achieved by the invention due to the fact that the first coupling part co-operating with the sealing surface is provided with at least one additional retaining means for the sealing device. The surprising advantage achieved as a result of this approach is that when the closure device is pierced by hollow needles or cannulas, which tend to have a somewhat larger external diameter, the flange-type shoulder of the sealing device is not pulled out of the locating region or only some

parts of it are. This situation usually occurs when using automated sample-taking systems, with which sampling needles or cannulas with an external diameter of between 0.8 mm and 2.5 mm, or even bigger up to 3.5 mm or 4.0 mm, are used, and not only is the sealing device pulled out of the locating region, at least some parts of it are also pulled into the interior of the housing container. Providing the retaining means prevents the flange-type shoulder of the sealing device from being pulled out of the locating region at the region where it merges with the sealing surface on the cap part of the cap, thereby enabling sample-taking instruments with a larger diameter to be reliably retained in the cap as described above, even if the friction forces between it and the material of the sealing device are higher. This improves operating safety during the entire process of handling such housing containers with the samples contained in them.

Also of advantage is another embodiment of the cap, in which the retaining means is provided in the form of at least one but preferably several projections since this enables a retaining force to be efficiently distributed around the periphery of the flange-type shoulder.

In another embodiment of the cap, the retaining means projects in the direction towards the other coupling part or projects into the locating region, the advantage of which is that friction between the retaining means and the flange-type shoulder of the sealing device can be increased depending on the size of the retaining means and, if necessary, a positive fit can be obtained in the abutment region between the flange-type shoulder and the coupling part.

In one embodiment of the cap, the retaining means is or are disposed on the first coupling part spaced at a distance back from the internal face in the direction towards the longitudinal axis, which means that the retaining action of the retaining means can be shifted to the transition region between the flange-type shoulder and the sealing element.

In another embodiment of the cap, in which a first retaining surface of the retaining means directed towards the internal face is aligned substantially parallel with the internal face, the flange-type shoulder is positively retained and optimally supported relative to a direction of radial movement thereof out of the locating region between the projections in the direction towards the longitudinal mid-axis.

Also of advantage is another embodiment of the cap, in which the retaining means is or are tapered starting from the first coupling part, and/or another retaining surface of the retaining means directed towards the longitudinal axis is inclined at an angle starting from the first coupling part towards the other coupling part running in the direction towards the internal surface, which provides a simple means of helping to force the material in order to form the flange-type shoulder, thereby obtaining both a non-positive and positive retaining system for the flange-type shoulder by the retaining means.

In another embodiment of the cap, the retaining means is provided in the form of segments of tubular sections and/or by a continuously extending hollow cylindrical component, the advantage of which is that it provides strong and highly retentive retaining means which, in co-operation with the sealing device, enables the flange-type shoulder to

be retained in the cap in a very stable arrangement which capable of withstanding strong forces that would otherwise tend to pull it out.

In other embodiments of the cap, at least one of the coupling parts is provided in the form of at least one web-type projection and/or at least some of the individual projections of the first coupling part extend from the locating region towards the end remote therefrom in the direction towards the first open end and/or at least one of the coupling parts is provided in the form of a hollow cylindrical projection, as a result of which a continuous seating or support surface is provided for the flange-type shoulder, in addition to which greater strength can be imparted to at least certain regions of the cap casing between the open end and the first coupling part.

In the embodiment of the cap in which the first coupling part co-operating with the sealing surface is provided with at least one additional retaining means for the sealing device, the retaining force of the flange-type shoulder in the cap can be further enhanced in order to trap the sealing element.

The objective of the invention is also independently achieved by the sealing device because at least one split is provided in the material, for example a cut, starting from the first end region and extending in the direction towards the other end region. The surprising advantage achieved as a result of this feature is that the material split contained within at least certain regions of the sealing device prevents friction forces from occurring during piercing by the hollow needle or cannula, thereby reducing compression forces in the direction of the longitudinal axis, and preventing any of the material of the sealing de-

vice from being punched out, even if using bigger or thicker cannulas. Because a split is provided in the material of the sealing device, it merely has to be forced apart in order to penetrate it, and it is usually only in the end region - in other words in the region of the sealing device facing the interior of the housing container - that the material of the sealing device has to be forced apart by the hollow needle. As a result of providing the material split, the rest of the piercing process through the still fully closed material of the sealing device is assisted due to the fact that the cut faces have already been moved apart from one another.

In another advantageous embodiment of the sealing device, several material splits are provided, which facilitates the use of piercing tools of different shapes with a bigger external dimension.

In one embodiment of the sealing device the material splits extend at an angle to one another, perpendicular to the longitudinal axis and/or intersect one another and/or a longitudinal extension of the material split extends in a direction parallel with the longitudinal axis, the advantage of which is that it affords a pronounced piercing direction on the one hand and enables a permitted radial movement of the mutually facing cut faces for the piercing process.

In one embodiment which has proved to be of particular advantage, the material splits terminates within the sealing device and/or extends across the major part of a distance between the two end regions, which means that a vacuum can be maintained in the interior of the housing container or the vacuum pressure released for a longer period,

whilst the piercing action and the resultant compression forces in the direction of the longitudinal axis can be minimised, on the other hand.

In another advantageous embodiment of the sealing device, at least some of the individual material splits link the two end regions to one another, further facilitating the piercing of the sealing device by the cannula.

Advantages are also to be had from other embodiments of the sealing device in which respective mutually facing cut faces of the material split sit in tight abutment with another in the position assumed on insertion in the housing container and/or the respective mutually facing cut faces abut in a gas-tight fit and/or the respective mutually facing cut faces abut in a liquid-proof fit, since this enables the interior to be adequately sealed off from external ambient conditions, even if there is a total continuous separation between the end regions of the sealing device, at the same time easing the degree of force which has to be applied for piercing.

In view of the fact that at least certain regions of the respective mutually facing cut faces of the material slit are flat and/or profiled, the retaining force acting between the mutually facing cut faces in the direction of the longitudinal axis can be selectively acted on, as a result of which any mutual relative shifting in the direction of the longitudinal axis can be controlled.

In another embodiment of the sealing device, at least one sealing means is introduced into at least certain regions between the cut faces, which means that the seal can

be further improved in the region of the material split if the interior of the housing container is evacuated.

In another possible embodiment of the sealing device, a recess is disposed in at least certain regions of a transition region between the flange-type shoulder and the sealing element, extending from the sealing surface in the direction towards the longitudinal axis, the advantage of providing the recess being that, the during the piercing motion as the cannula is being inserted through the sealing device, the deformation imparted to the flange-type shoulder is shifted in the direction of the sealing element inserted in the interior on the one hand, and an improved pinching and retaining force can also be obtained by adapting the coupling part accordingly, on the other hand.

Other advantageous embodiments of the sealing device and the resultant advantages may be found in the detailed description.

The objective of the invention, namely to propose a closure device for a housing container which is open at one of its end faces, is also independently achieved due to the fact it incorporates a cap as proposed by the invention and, inserted in it, a sealing device proposed by the invention. The closure device obtained by combining the cap with the sealing device offers a high degree of operating safety due to the co-operation of these two constituent parts, especially in the area of the coupling mechanism between the cap and the sealing device. As a result, any relative movement between the flange-type shoulder of the sealing device and the locating region of the cap is virtually or completely prevented in automated sampling systems.

In one embodiment of the closure device, the retaining means of the cap co-operates with the flange-type shoulder of the sealing device and/or the retaining means is or are positively connected to the sealing device, in particular the flange-type shoulder, thereby permitting co-operation between the retaining means and the flange-type shoulder of the sealing device, as a result of which the compression forces created by the sampling tool of the sampling system are transmitted into the retaining means as the material of the sealing device is separated, thereby generating an adequate retaining force for the flange-type shoulder.

In another embodiment of the closure device, at least one recess provided in the sealing device and complements the retaining means, the advantage of which is that the sealing device can be positively retained in the cap, further improving retention force.

Another embodiment of the closure device is possible in which a recess is provided in at least certain regions where the flange-type shoulder merges into the sealing element, extending from the sealing surface in the direction towards the longitudinal axis, and the recess essentially complements the first coupling part in the cap, the advantage of the recess being that the deforming motion introduced into the sealing device during the piercing motion of the cannula can be shifted away from the flange-type shoulder in the direction towards the sealing element inserted in the interior, on the one hand, and the coupling part, adapted accordingly, creates an even better pinching effect and retaining force.

In another embodiment of the closure device, an external dimension of the recess in a plane perpendicular to the longitudinal axis is the same as or bigger in the radial

direction than the clearance dimension, in particular the internal diameter of the first coupling part co-operating with the sealing surface, the advantage of providing a recess in the sealing device being that the sealing device can also be pinched by means of the coupling part in the region where the flange-type shoulder merges with the sealing element, thereby retaining the latter in the cap.

Another embodiment of the closure device is also of advantage in which a retaining ring is provided in the locating region between the flange-type shoulder of the sealing device and the coupling part of the cap disposed at the end remote from the housing container, and/or a thickness of the flange-type shoulder of the sealing device in the non-assembled state is bigger than a distance between the two coupling parts in the direction of the longitudinal axis less a thickness of the retaining ring, because it significantly facilitates assembly of the sealing device in the cap and does so without causing it to be extensively deformed in the region of the flange-type shoulder, up to the point at which it assumes the correct position in the container chamber between the two coupling parts.

The objective is also independently achieved by the invention as a result of the container system having a housing container with at least one end face open, which is then closed off by a closure device as proposed by the invention. The advantages obtained as a result of the combination of features defined in this claim reside in the fact that a container device is provided with a closure mechanism which affords a sufficiently solid connection between the flange-type shoulder of the sealing device and the coupling parts in the cap, which is guaranteed to prevent any tearing out, thereby offering a high degree of operating safety during use and enabling a sample to be taken rapidly.

In another embodiment of the container device, an internal clearance dimension, in particular a diameter, of the first coupling part co-operating with the sealing surface is the same as or smaller than an internal clearance width, in particular an internal diameter, of the housing container in the region of its open end face, the advantage of which is that the open end face of the housing container sits flat against the coupling part and also projects in the direction towards the longitudinal axis, thereby improving the pinched retention of the sealing device in this region and producing a higher retaining force for the sealing device inside the cap.

Finally, in another embodiment of the closure device, the internal clearance width, in particular the diameter, may be between 0 % and 30 % smaller than the internal clearance width, in particular the internal diameter of the housing container, in the region of its open end face so that the pinching effect and hence clamping of the sealing device in the cap can be easily fixed, depending on the dimension of the coupling parts projecting out from the internal surface in the direction towards the longitudinal axis.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be explained in more detail below with reference to examples of embodiments illustrated in the appended drawings. Of these:

FIG. 1 is a simplified, schematic diagram showing a side view of the container system in section;

FIG. 2 is a simplified diagram of the container system illustrated in Fig. 1 on an enlarged scale but before the sealing device has been inserted in the housing container;

FIG. 3 is a simplified, schematic diagram showing a side view in section of another embodiment of the cap;

FIG. 4 is a simplified, schematic diagram showing a side view in section through another possible embodiment of the cap;

FIG. 5 is a simplified, schematic diagram showing a side view in section of another embodiment of the sealing device, which may be construed as an independent embodiment in its own right;

FIG. 6 is a simplified, schematic diagram showing a side view in section, along line VI-VI indicated in Fig. 7, of another possible embodiment of a sealing device, which may be construed as an independent embodiment in its own right;

FIG. 7 is a simplified, schematic diagram showing a plan view of the sealing device illustrated in Fig. 6.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Firstly, it should be pointed out that the same parts described in the different embodiments are denoted by the same reference numbers and the same component names

and the disclosures made throughout the description can be transposed in terms of meaning to same parts bearing the same reference numbers or same component names. Furthermore, the positions chosen for the purposes of the description, such as top, bottom, side, etc,. relate to the drawing specifically being described and can be transposed in terms of meaning to a new position when another position is being described. Individual features or combinations of features from the different embodiments illustrated and described may be construed as independent inventive solutions or solutions proposed by the invention in their own right.

The embodiments illustrated show different variants of the closure device and the components from which it is made, as well as the resultant container system, although it should be pointed out at this stage that the invention is not restricted to the embodiments and variants illustrated here, but also encompasses various combinations of the individual embodiments with one another, all of these various options being within the reach of the person skilled in the art based on the teaching of the technical aspects of the invention described here. Accordingly, all conceivable variants which may be obtained by combining individual features of the illustrated and described embodiments are also included within the scope of the invention.

Figs. 1 and 2 illustrate one possible embodiment of the container system 1, which may be construed as an independent embodiment in its own right, which is preferably used in medical technology as a means of containing body fluids and cellular elements. One special application is that of taking blood samples, in which case the pressure in the interior of the container system 1 is lower than atmospheric pressure, as is generally the

case with such tubes used for taking blood samples.

In the embodiment illustrated as an example here, the container system 1 has a housing container 2 and at least one closure device 3 for an end face 4 of the housing container 2, which is open in this particular case. A container wall 5 bounds an interior 7 in the region of a longitudinal axis 6, and the end face 9 of the housing container 2 remote from the opposite end face 4 is closed off by an end wall 8.

As an alternative to the above, however, it would also be possible for the end face 9 which is closed in this example to be open instead, in which case the end wall 8 could be partially or totally dispensed with, to enable the closure device 3 described above to also be fitted in the region of the other end face 9. However, it would also be possible for this other end face 9 to be fitted with a closure device 9 other than the one just described above, in which case the end face 4, which is open in this example, or the other end face 9 could also be used to permit easy access to the interior 7 of the housing container 2.

The housing container 2 may be made from a variety of materials, such as glass, plastic, etc., and an external and/or internal surface of the housing container 2 may be provided with a coating in at least certain regions or on its entire surface. This coating might be applied as a means of reducing or preventing the susceptibility of the sample to adhere to the internal and/or external wall of the housing container 2, for example, or alternatively to provide a barrier layer preventing ingress of external ambient air or to prevent or minimise leakage of the sample material from the interior.

The external and internal dimensions of the housing container 2 may be virtually constant along its entire longitudinal extension as viewed along the longitudinal axis 6 - in other words cylindrical - but it may also taper from a larger dimension to a smaller dimension, in a manner that has long been known from the prior art.

In the embodiment illustrated as an example here, the closure device 3 comprises a cap provided with at least one sealing device 11 which is retained therein or thereon. A coupling mechanism 12 is provided between the cap 10 and the sealing device 11 in order to fix them in their mutual position. In the region of its open end and co-operating therewith, the sealing device 11 has a sealing surface 14 directed towards an internal surface 13 of the housing container 2, which closes off the interior 7 in the region of the open end face 4 when the sealing device 11 is inserted, in particular rendering it gas-tight and liquid-proof.

As described above, the cap 10 is designed to accommodate a sealing device 11 which can be pierced, and the sealing device 11 has an external surface 15 with at least certain regions which can be inserted in the open end face 4 of the housing container 2 and forms the sealing surface 14. The cap 10 also has a cap casing 16 which engages or fits round at least certain regions of the housing container 2, which, depending on the process used to manufacture the cap 10, will either by a hollow cylinder or a hollow truncated cone. Disposed on at least an internal face 17 of the cap casing 16 are at least two coupling parts 18, 19 forming part of the coupling mechanism 12, which are joined thereto so that they can be displaced. Accordingly, the first coupling part 18 is directly adjacent to the open end face 4 of the housing container 2 and the other coupling part 19 is spaced at a

distance apart in the direction of the longitudinal axis 6. The two coupling parte 18, 19 are preferably disposed in planes extending perpendicular to the longitudinal axis 6 and the two coupling parts 18, 19 extend round the internal face 17 of the cap casing 16 or cap 10, projecting out in a radial direction towards the longitudinal axis 6, thus forming a locating region 20 between them.

In order to fit round the open end face 4 of the housing container 2, at least a first end 21 of the cap 10 is open, whilst another end 22 may be closed in at least certain regions, preferably in the region of the cap casing 16. To avoid unnecessary repetition, reference may be made to European patent EP 0 419 490 B1 and also European patent EP 0 445 707 B1 by the same applicant for details of the design of the closure device, in particular the cap and sealing device, and how it fits on the housing container, these disclosures being included in this patent by reference. The same applies to the design of the coupling mechanism 12 between the cap 10 and sealing device 11, as well as the orifice or bore in the cap 10 and the retaining ring in the region of the longitudinal axis 6 to enable piercing by the sealing device 11.

The sealing device 11 is designed to be retained in the locating region 20 formed inside the cap 10 and has a sealing element 23 provided with a sealing surface 14, at least some regions of which co-operate with the open end face 4 of the housing container 2, and at least one preferably continuous flange-type shoulder 24 which projects radially outwards from the sealing surface. The shoulder is likewise an integral part of the coupling mechanism 12 between the cap 10 and sealing device 11 and projects into the locating region 20 between the two coupling parts 18, 19 of the cap 10. The flange-type shoulder 24

constitutes a first end region 25 of the sealing device 11 and the sealing element constitutes the other end region 26 thereof.

As described above, the first coupling part 18 projects out from the internal face 17 of the cap casing 16 in a radial direction towards the longitudinal axis 6 and is disposed between the shoulder 24 of the sealing device 11 and the open end face 4 of the housing container 2. If the other end 22 of the cap 10 is also of a virtually open design, as is the case in the embodiment illustrated as an example here, an additional retaining ring 27 may be provided between the shoulder 27 of the sealing device 11 and the other coupling part 19 in order to fix the position of the shoulder 24 in the locating region 20. This provides an easy means of inserting the sealing device 11 from the other end 22 of the housing container 2 remote from the first end 21 and pushing the sealing element 23 through the free space in the region of the first coupling part 18 until the shoulder 24 abuts with the first coupling part 18. To facilitate insertion, the other coupling part 19 extends out from the internal face 17 of the cap casing 16 by a relatively short distance and it is the additionally inserted retaining ring 27 which fixes the relative position between the cap 10 and the sealing device 11. As mentioned above, this system is explained in more detail in and protected by patent EP 0 445 707 B1 filed by the same applicant.

If no retaining ring 27 is used, on the other hand, at least certain regions of the other end 22 of the cap 10 are closed off by an end wall, not illustrated, although a space must always be left free in the region of the longitudinal axis 6 to allow a hollow needle or cannula to be inserted through the sealing device 11 into the interior 7.

To ensure that the sealing surface 14 is correctly seated on the internal face 13 of the housing container 2, at least the sealing element 23 of the sealing device 11 is made from a highly elastic material which also has self-sealing properties after piercing and when subsequently removing a hollow needle or cannula or such like. To ensure that the sealing surface is correctly biassed and sits in tight abutment with the internal face 13, the sealing element 23 has a bigger external dimension 28, in particular a bigger external diameter 29, than an internal clearance width 30, preferably an internal diameter 31, of the housing container 2 in the region of the open end face 4, as may best be seen from Fig. 2. This being the case, it has proved to of advantage if the difference between the bigger external dimension 28 in the non-biassed state and the internal clearance width 30 is within a lower range of between 2 % and 5 % and within an upper differential range of between 7% and 20 % by reference the bigger external dimension 28. Accordingly, the difference is preferably between 2 % and 20 %, more preferably between 4 % and 10 % and even more preferably between 5 % and 7 %.

Turning back to the simplified diagram shown in Fig, 1 in which the sealing device 11 is shown in the inserted position in the housing container 2, at least the sealing element 23 is in the biassed state. To fix the sealing device 11 relative to the cap 10 or housing container 2 in a better and more stable position, an internal clearance dimension 32, in particular an internal diameter 33, of the first coupling part 18 co-operating with the sealing surface 14 is smaller, although this is over-exaggerated in the drawing, than the external dimension 28, in particular the external diameter 29, of the sealing device 11 to be accommodated in the region of its sealing surface 14 in the undeformed or non-biassed state, the basis for reference being the external dimension 28 or external diameter 29. A

lower threshold value of between 5 % and 15 % and an upper threshold value of between 16 % and 25 % have proved to work efficiently. Accordingly, the differences may therefore be between 5 % and 25 %, preferably between 10 % and 20 % and even more preferably between 13 % and 17 %. This enables the sealing device 11 to be trapped to a certain degree by the coupling part 18 in the region where the sealing element 23 and the flange-type shoulder 24 merge.

As the sealing device 11 is pierced by the cannula or similar elements or components, the friction forces between the material of the sealing device 11 and the piercing element generate a force, schematically indicated by arrow "F", on the sealing device 11 in its central region – in other words in the area of the longitudinal axis 6. The shoulder 24 is seated on the support surface of the first coupling part 18, which in this instance is virtually flat and extends perpendicular to the longitudinal axis 6, to a certain degree only as a result of the internal dimension 32 and the bitter internal diameter 33 of the coupling part 18. As the internal dimension 32 or internal diameter 33 is smaller in size, an appropriate biassing force still has to be applied from the first coupling part 18 towards the sealing element 23, transmitting the force indicated by arrow "F2 expended by the flange-type shoulder 24 to the abutment surface of the first coupling part 18, without pulling the flange-type shoulder 24 out of the locating region 20 due to elastic deformation, so that the sealing device 11 is pushed at least partially into the interior 7 of the housing container 2.

As very schematically illustrated, in the region of the open end face 4 of the housing container 2, the first coupling part 18 projects out from the internal face 17 in the direction towards the longitudinal axis 6, the internal dimension 32 or internal clearance

diameter 33 in the region of the first coupling part 18 being at least the same as but preferably smaller than the internal clearance width 31 or internal diameter 31 of the housing container 2 in the region of the open end face 4. Depending on the size of the housing container 2 and the associated closure device 3, a lower threshold value for the difference may be between 0 % and 15 % and an upper threshold value may be between 16 % and 30% based on the internal clearance width 30 or clearance diameter 31 of the housing container 2 by reference to the internal clearance dimension 32 or internal diameter 33 of the coupling part 18. Accordingly, the difference may also be between 7 % and 12 % , for example. As a result, the coupling part 18 projects out from the internal surface 13 in the direction towards the longitudinal axis 6. The specific dimensions given here are intended merely as an example of one possible embodiment of a container system with a nominal size of 13 mm.

clearance width 30 or internal diameter 31:	10.55 mm
internal clearance dimension 32 or diameter 33:	9.60 mm
non-spanned external dimension 28 or diameter 29:	11.20 mm

As may also be seen from Fig. 1, at least one of the coupling parts 18, 19 is provided in the form of a web-like projection 34, which projection may be disposed in intermittent regions around the periphery or alternatively run continuously around it on the internal face 17 of the cap 10.

Fig. 3 is a diagram in section on a very much enlarged scale, illustrating another embodiment of the cap 10, which may also be construed as a separate solution, the

same reference numbers and the same component names being used to denote the same parts as those described in connection with Figs. 1 and 2 above. To avoid unnecessary repetition, reference should be made to the more detailed descriptions of Figs. 1 and 2 given above.

In the embodiment illustrated as an example here, the coupling part 18 is provided in the form of several projections 34 distributed around the periphery. The other coupling part 19 may also be divided into segments distributed around the periphery. The locating region 20 for the flange-type shoulder 24 is in turn provided between the coupling parts 18, 19. As illustrated in a very simplified manner in the region of the coupling parts 18, at least some of the individual projections 34 of the first coupling part 18 extend out from the locating region 20 towards the side end therefrom in the direction towards the first open end 21 of the cap 10. These parts or ribs of the projections 34, on the one hand, are able to minimise or prevent any relative shifting of the cap 10 with respect to the housing container 2 in the direction perpendicular to the longitudinal axis 6 when the open end face 4 is in the closed position, and on the one hand, facilitate the task of placing the closure device 3 as a unit on the open end face 4 of the housing container 2, because these part regions of the projections 34 fulfil a centring function to a certain degree.

When the sealing device 11 is inserted from the first, in this case open end 21 into the cap 10, this part region of the projections 34 serves as a guiding aid and deforms the shoulder 24 until it has assumed its correct position in the locating region 20.

In order to obtain a flat seating of the first coupling part 18 on the open end

face 4, it is of advantage to provide the coupling part 18 or the projection 34 forming it as a hollow cylindrical projection. The same naturally applies to the other coupling part 19.

As described above in connection with Fig. 1, it is of advantage to provide the retaining ring 27 in order to fix the position of the shoulder 24 in the locating region 20 between the flange-type shoulder 24 of the sealing device 11 and the other coupling part 19 of the cap 10 at the end remote from the housing container 2. Consequently, the internal clearance dimension or diameter in the region of the other coupling part 19 may be selected so that it is just big enough to snap the retaining ring 27 into the locating region in a positive fit. This is very easily done due to the elastic deformation of the material of the cap, which is made from plastic. This also makes the process of inserting the sealing device 11 in the cap 10 much easier, without deforming the sealing device 11. It would also be possible for a thickness of the flange-type shoulder 24 of the sealing device to be bigger in the direction of the longitudinal axis 6 in the non-assembled state than a distance between the two coupling parts 18, 19 in the same direction, less a thickness 35 of the retaining ring 27, also in the direction of the longitudinal axis 6. The shoulder 24 is therefore biassed inside the locating region 20 between the two coupling parts 18, 19, in which case the contact force, in particular on the first coupling part 18 and hence the resultant adhesive friction between it and the shoulder 24 can be improved depending on the biassing pressure.

Fig. 4 illustrates another possible embodiment of the cap 10, the same reference numbers and component names being used as those used in connection with Figs. 1 to 3 described above. To avoid unnecessary repetition, reference should be made to the more detailed description given above with reference to Figs. 1 to 3.

In order to retain the sealing device 11, which is not illustrated in detail, it may be of advantage to provide at least one retaining means 36 for the sealing device 11 in the region of the first coupling part 18 co-operating with the sealing surface 14. This being the case, the retaining means 36 may be provided in the form of one but preferably several projections 37. The retaining means 36 or the projections 37 constituting them, thus project from the first coupling part 18 in the direction towards the other coupling part 19 so that at least some of their regions extend into the locating region 20. The degree to which the retaining mans 36 projects out from a surface profiling beyond the coupling part 18 may be less than 1.0 mm, e.g. 0.5 mm and smaller, but also bigger than 1.0 mm, e.g. between 1.5 mm and 3.0 mm, depending on the retaining force which needs to be obtained..

In order to reduce or prevent the likelihood of the flange- -type shoulder 24, not illustrated, being torn out, the retaining mans 36 is or are disposed on the first coupling part 18 at a distance from the internal face 17 in the direction towards the longitudinal axis 6. It has proved to be of particular advantage if the retaining means 36 is or are arranged in the region of the first coupling part 18 adjacent to the region lying immediately adjacent to the longitudinal axis 6, in other words in the peripheral region. This being the case, a first retaining surface 38 of the retaining means 36 directed towards the internal face 17 may extend substantially parallel with the internal face 17. A simple and effective elastic de-formation of the sealing device 11 in the transition region between the sealing element 23 and the flange-type shoulder 24 can be achieved by using retaining means 36 which taper starting from the first coupling part 18 in the direction towards the other coupling part 19. Accordingly, another retaining surface 39 of the retaining means 36 directed towards the longitudinal axis 6 extends at an angle starting from the first coupling part 18 towards the

other coupling part 19 in the direction towards the internal face 17. Consequently, the retaining means 36 are of a triangular shape as viewed in cross section, as illustrated in the left-hand part of Fig. 4.

The right-hand part of Fig. 4 illustrates another possible embodiment of the retaining means 36 on the coupling part 18, which has a substantially rectangular cross section and is made up of segments 40 of tubular section, for example. Naturally, however, it would also be possible for the retaining means 36 to be provided in the form of a peripheral, continuously extending hollow cylindrical component. It should be pointed out that the retaining means 36 may have variously shaped cross sections and that any layout around the periphery may be selected. In order to facilitate assembly and obtain the correct mutual orientation, it is preferable to opt for a continuous arrangement around the entire periphery. The retaining means 36 of the cap 10 co-operate with the flange-type shoulder 24 of the sealing device 11, although this is not illustrated, and may be connected to the sealing device 11, in particular the flange-type shoulder 24, in a positive fit.

As an alternative or in addition to the above, however, it would also be possible for at least certain regions of the bearing surface of the coupling part 18 directed towards the flange-type shoulder 24 to be provided with profiling on the surface.

This profiling on the bearing surface may form individual coupling parts of a coupling mechanism, and may naturally be of any geometric shapes known from the prior art, such as pyramids, triangular pyramids, truncated pyramids, regular or irregular polygons, cones, truncated cones, prism-shaped and many other options. The essential

point is that this bearing surface has this profiling on at least some of and preferably its entire surface, in order to form another additional retaining means in co-operation with the support surfaces of the flange-type shoulder 24 directed towards it.

As illustrated in a very simplified format, the other coupling part 19 extends farther out from the internal face 17 in the direction towards the longitudinal axis 6 than the one illustrated in Fig. 3. It may also be provided with additional connecting webs.

Fig. 5 is a simplified schematic diagram on an enlarged scale and in section showing the design of the closure device 3 and sealing device 1, the same reference numbers and component names being used for the same parts as those described in connection with Figs. 1 to 4 above. To avoid unnecessary repetition, reference may be made to the more detailed descriptions given with reference to Figs. 1 to 4.

In the area on the left-hand side, at least one recess 41 is illustrated in simplified format, which complements the retaining means 36 illustrated in Fig. 4 and extends back into the flange-type shoulder 24. The recess or recesses may be disposed in the sealing device 11 to match the cross section and three-dimensional shape of the retaining means 36 selected from the options described above in connection with Fig. 4. In order to improve the adhesive force, it would naturally also be possible for the recesses 41 to be slightly smaller than the retaining means 36, thereby obtaining an even higher retaining force and preventing tearing out due to the generally elastic deformation of the material used for the sealing device 11. In the right-hand part of Fig. 5, the design of the recess 41 complements the retaining means 35 illustrated in the right-hand part of Fig. 4.

As illustrated in a very simplified format, a recess 43 is also provided in a transition region 42 between the sealing element 23 and the flange-type shoulder 24, which extends out from the sealing surface 14 in the direction towards the longitudinal axis 6. This recess may also be of a design substantially complementing the first coupling part 18 in the cap 10, thereby enabling an efficient positive fit to be obtained between these components. By selecting the size and disposition of the recess 43 accordingly, the deformation and tearing force on the flange-type shoulder 24 when piercing the middle region of the shoulder 24 and sealing element 23 with the sampling tool, in particular the cannula, can be shifted away from the locating region 20 towards the sealing element 23. The disposition of the recess 43 may be selected either independently of or in conjunction with the disposition of the recesses 41 described above. Naturally, it would also be possible to provide one or more retaining means 36 on the cap 10, and the sealing device 11 could be inserted in the flange-type shoulder 24 merely by deforming or forcing the material thereof, without causing any damage to the material.

As described above, the first coupling part 18 in the plane disposed perpendicular to the longitudinal axis 6 has an internal clearance dimension 32 or an internal diameter 33 which is the same as or smaller than the external dimension 28 of the sealing device 11 in the region of its sealing surface 14 in the non-deformed or non-biassed state. If the recess 43 is provided, it may also be of advantage if an external dimension 44 of the recess 43 in the plane perpendicular to the longitudinal axis 6 is the same as or bigger than the internal clearance dimension 32, in particular the internal diameter 33, of the first coupling part 18 co-operating with the sealing surface 14 in the radial direction. In any event, the first coupling part 18 projects out from the inner surface 13 of the housing container 2

in the direction towards the longitudinal axis 6 and the sealing device 11 is pinched and hence retained in the cap 10 by the first coupling part 18. If the degree of this pinching effect is sufficient, the other coupling part 19 in the region of the other end 22 can be dispensed with, at least in certain regions or altogether.

Figs. 6 and 7 illustrate another possible embodiment of the sealing device 11, which may optionally also be construed as a separate embodiment in its own right, the same reference numbers and component names again being used to denote the same parts as those described in connection with Figs. 1 bis 5 above. Again, to avoid unnecessary repetition, reference may be made to the more detailed description of Figs. 1 to 5. Naturally, any combinations of the different retaining means 36 and recesses 41 would be possible.

To make it easier to pierce and separate the material of the sealing device 11, it may be of advantage, either as a feature on its own or in combination with the embodiments described above, if at least one material split 45 is provided, starting from the first end region 25 in the region of the flange-type shoulder 24 and extending in the direction towards the other end region 26, and, as illustrated in a very simplified format, this may be in the form of one or more cuts. Usually, several material splits 45 are provided, in which case they extend at an angle to one another and are oriented in a plane perpendicular to the longitudinal axis 6, as may best be seen from Fig. 7. If several material splits 45 are provided, they may be either separate from one another or may also join with one another. Extending at an angle to one another, the individual material splits intersect in the region of the longitudinal axis 6. Another possible layout of the material split 45 - which is substantially Z-shaped - is indicated by dotted-dashed lines in Fig. 7. Naturally, any design and

disposition may be selected for material split or material splits 45 relative to one another. To facilitate piercing, a longitudinal extension of the material split 45 or material splits 45 extends in the direction parallel with the longitudinal axis 6.

By material split is meant that the material from which the sealing device 11 is made is cut in at least certain regions of this area. As a result, the component made from this material constitutes an essentially integral unit but the integrity of this material is interrupted in the region of the material split.

As may be seen from Fig. 6, the material split 45 extends across the major part of a distance 46 between the two end regions 25, 26, and then terminates within the sealing device 11. In this respect, it has been found that a dimension of at least half the distance 46 is practical. However, this dimension could also be between 60 % and 80 % or also between 2/3 and ¾ of the distance 46.

As an alternative to the above, however, it would also be possible for at least some of the individual material splits 45 to link the two end regions 25, 26 to one another, as indicated by broken lines. This will depend on whether sufficient biassing can be obtained, thereby securing a sealing abutment of the material splits 45 without having a detrimental effect on the shelf life to the time of use and ensuring that the system can still be used in accordance with the specified instructions without the sample being affected.

When the closure device 3 is in the inserted position, in particular when the sealing element 23 is fitted in the housing container 2, mutually facing cut faces 47, 48 of

the material split 45 should sit in tight abutment with one another and in particular should be gas-tight and/or liquid-proof.

A transverse extension of the material split 45 towards the sealing surface 14 should be dimensioned such that the material split 45 terminates at least before the sealing surface 14 so that the sealing element 23 is intrinsically closed in the region of the sealing surface 14, as viewed around the periphery. The thickness of the non-split material between the material split 45 and the sealing surface 14 will depend on the intended use of the container system 1 and, this being the case, if a vacuum pressure is to prevail in the interior 7, care must be taken to ensure that there will be no pressure compensation with the external ambient environment for a long period. If, on the other hand, the closure device 3 is placed on a housing container 2 in which the interior 7 is at the same pressure as the ambient pressure, the material split 45 may also extend as far as the sealing surface 14. Provided an adequate seal can be obtained, however, the material split 45 may extend as far as the sealing surface 14, even if the container systems 1 are to be evacuated.

As may also be seen from Fig. 6, the mutually facing cut faces 47, 48 of the material split 45 are flat in at least certain regions. In addition, however, it may also be of advantage if mutually facing cut faces 47, 48 of the material split 45 are profiled in at least certain regions.

The material split 45 described here is preferably provided in the form of a flat or smooth cut or cuts, although it is possible to provide a certain amount of profiling between the mutually facing cut faces 47, 48. If the mutually facing cut faces 47, 48 have

only a minimal surface roughness, which is enough to produce an adequate sealing effect between the two mutually spaced apart end regions25, 26 when the split surfaces are pressed one against the other, this will nevertheless facilitate the process or piercing with the cannula or any other sampling means. As a result of the radial compression forces which occur during insertion through the sealing device 11, in particular the sealing element 23 with the surface 13 in the open end face 4 of the housing container 2, the respective mutually facing cut faces 47, 48 of the material splits 45 are pressed against one another which, as a result of the profiling, prevents any relative mutual shifting between them in the direction of the longitudinal axis. As the cannula is inserted through the material split, the two mutually facing cut faces 47, 48 are pushed apart from one another in the radial direction relative to the longitudinal axis 6 due to the elastic deformability of the material, so that the cut faces 47, 48 which stick together in a positive and friction-induced fit are moved apart in at least certain regions. Consequently, the cannula can be inserted through the sealing device 11 with less effort, which totally or largely prevents any unintended displacement of the flange-type shoulder 24 relative to the locating regions 20 of the cap10, as described above.

This profiling may be of various types but is illustrated as a basic wave-shaped arrangement in Fig. 6 for the sake of simplicity.

However, it would also be possible to introduce a sealing means 49, indicated by circles in the left-hand half of Fig. 6, in at least certain regions between the cut faces 47, 48. This sealing means 49 may be of any consistency and may have adhesion properties, although care should be taken to ensure that the sealing means 49 can not get

into the interior 7 of the housing container 2 when the sealing device 11 is pierced by a cannula or such like in the region of the material split 45, or the sealing means 49 is selected such that if it comes into contact with the sample contained in the interior 7, it does not detrimentally alter it or compromise subsequent evaluation of the sample or its shelf life.

. As described above, at least parts of the sealing device 11 are made from a self-sealing, highly elastic material, selected from the group consisting of synthetic or thermoplastic elastomers. However, it would also be possible for at least a surface section thereof to be provided with a coating 50 in the region of the sealing element 23, as very simply illustrated in Fig. 6 by broken lines, on the side facing the interior 7 of the housing container 2. Naturally, surface sections spaced at a distance therefrom, such as the end region 15 with its recess, may also be provided with this coating 50. This being the case, the coating 50 may be selected from the group consisting of silicone oils and may be of a type which repels body fluids and/or repels cellular elements thereof. The force to be applied to the cannula in order to pierce the sealing device 11 can be reduced as a result.

For the sake of good order, it should be pointed out that in order to provide a clearer understanding of the structure of the container system 1, it and its constituent parts are illustrated to a certain extent out of proportion and/or on an enlarged scale and/or on a reduced scale.

The underlying objectives of the solutions proposed by the invention may be found in the description.

Above all, the individual embodiments of the subject matter illustrated in Figs. 1, 2; 3; 4; 5; 6, 7 may be construed as independent solutions proposed by the invention. The objectives and associated solutions may be found in the detailed description of the drawings.

List of Reference Numbers

1	Container system	23	Sealing element
2	Housing container	24	Shoulder
3	Closure device	25	End region
4	End face	26	End region
5	Container wall	27	Retaining ring
6	Longitudinal axis	28	External dimension
7	Interior	29	Diameter
8	End wall	30	Clearance width
9	End face	31	Diameter
10	Cap	32	Internal dimension
11	Sealing device	33	Diameter
12	Coupling mechanism	34	Projection
13	Surface	35	Thickness
14	Sealing surface	36	Retaining means
15	Surface	37	Projection
16	Cap casing	38	Retaining surface
17	Internal face	39	Retaining surface
18	Coupling part	40	Segment
19	Coupling part	41	Recess
20	Locating region	42	Transition region
21	End	43	Recess
22	End	44	Transition region

45 Material split

46 Distance

47 Cut face

48 Cut face

49 Sealing element

50 Coating